IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SEPRACOR INC., Plaintiff, v. DEY, L.P. and DEY, INC., Defendants.	C.A. No. 06-113-KAJ

SEPRACOR INC., Plaintiff, v. DEY, L.P. and DEY, INC., Defendants.	C.A. No. 06-604-KAJ

PLAINTIFF SEPRACOR INC.'S ANSWERING BRIEF IN OPPOSITION TO MOTION OF DEFENDANTS DEY, L.P. AND DEY, INC. TO CONSOLIDATE ACTIONS

November 7, 2006

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This brief by Sepracor Inc. ("Sepracor") is in response to the motion, and corresponding memorandum, of Dey, L.P. and Dey, Inc. (collectively "Dey") to consolidate the recently filed Civil Action No. 06-604-KAJ ("Dey II") into the earlier filed Civil Action No. 06-113-KAJ ("Dey I") without any modification of the Scheduling Order (D.I. 30) in the earlier filed action.

Sepracor does not oppose the general concept of consolidating the above-captioned actions. However, the Dey I action and the Dey II action are based on two different Abbreviated New Drug Applications ("ANDAs") filed by Dey with the U.S. Food and Drug Administration ("FDA") at considerably different times and relating to different infringing products. Therefore, procedurally, Sepracor opposes the portions of Dey's consolidation motion that refuse to permit any modification of the Dey I Scheduling Order to account for the newly filed Dey II case. Consolidation without modification of the Dey I Scheduling Order would preclude Sepracor from having a fair and reasonable opportunity to discover and prepare the issues on which it has the burden of proof in the Dey II case.

I. THE APPLICABLE LEGAL STANDARDS

There is no dispute that Rule 42(a) requires, at a minimum, the existence of a common question of law or fact for consolidation. *See* DEY'S MEMORANDUM IN SUPPORT OF ITS MOTION TO CONSOLIDATE ("DEY'S MEMORANDUM") at 3, lines 11-13. However, this Court has discretion with respect to consolidation of actions. FED. R. CIV. P. 42(a); *U.S. v. Denstply Int'l, Inc.*, 190 F.R.D. 140, 142-43 (D. Del. 1999); *La Chemise Lacoste v. The Alligator Co.*, 60 F.R.D. 164 (D. Del. 1973) (recognizing that "[w]hether consolidation should be ordered is a matter of sound judicial discretion" and denying

consolidation). Consolidation of actions, even those involving common questions of law or fact, is not automatic as "the trial court must balance the probable savings of time and effort against the likelihood that a party might be prejudiced . . . ." *Paul Bernardi v. City of Scranton*, 101 F.R.D. 411, 413 (M.D. Pa. 1983) (citing *Rohm & Haas Co. v. Mobil Oil Corp.*, 525 F. Supp. 1298, 1309 (D. Del. 1981)).

II. DEY'S GAMESMANSHIP SHOULD NOT BE PERMITTED TO PREJUDICE SEPRACOR

A. Background

Under the provisions of the Hatch-Waxman Act, the ANDA applicant has control over the timing as to when the patentee files these types of "paragraph IV" litigations. In particular, when a generic drug applicant files an ANDA with a paragraph IV certification, the ANDA applicant must provide notice to the innovator drug company and patentee. 21 U.S.C. § 355(j)(2)(B)(i)-(ii). The patentee then has forty-five days upon receipt of such notification to file a patent infringement lawsuit under the provisions of the Hatch-Waxman Act. 21 U.S.C. § 355(j)(5)(B)(iii).

Here, Dey initially filed ANDA No. 77-800 with a paragraph IV certification seeking to copy three of Sepracor's highly successful drug products. *See* DEY'S MEMORANDUM at 2, lines 6-8 (defining Sepracor's three products as Sepracor's "'levalbuterol hydrochloride solutions'"). In a letter dated January 9, 2006, Dey provided notice to Sepracor that it filed ANDA 77-800 seeking to copy Sepracor's "levalbuterol hydrochloride solutions." On February 22, 2006, within the forty-five day period provided under the Hatch-Waxman Act, Sepracor filed suit in connection with Dey's ANDA No. 77-800. This case was assigned Civil Action No. 06-113-KAJ.

Dey's notice letter of January 9, 2006 was the second notice letter that Sepracor received by a generic ANDA applicant relating to copies of Sepracor's "levalbuterol hydrochloride solutions." The first notice letter was received from Breath Limited. Thus, by the time Sepracor received Dey's notice letter of January 9, 2006 Sepracor had already filed suit pursuant to the Hatch-Waxman provisions against Breath Limited ("Breath") in the District of Massachusetts. *Sepracor Inc. v. Breath Ltd.*, No. 06-10043-DPW (D. Mass.) (currently pending).

After receiving Dey's notice letter of January 9, 2006, and prior to bringing any action under the Hatch-Waxman Act, Sepracor had initiated a number of discussions with Dey and its counsel regarding consolidation of any such action against Dey with the already filed litigation against Breath in Massachusetts so as to have all of the generic challenges relating to copies Sepracor's "levalbuterol hydrochloride solutions" together. *See, e.g.*, E-MAILS ON FEBRUARY 7, 2006 BETWEEN DADIO AND KLING (attached hereto as Appendix A) At that time, a scheduling order had not been entered in the Breath litigation. *See* SCHEDULING ORDER ENTERED IN *SEPRACOR INC. V. BREATH LTD.*, NO. 06-10043-DPW (D. MASS.) ON MAY 3, 2006 (attached as Appendix A to D.I. 24). Dey would not agree to make consolidation possible. Sepracor nevertheless continued its efforts to make consolidation possible. However, Dey's counsel represented to this Court that, *inter alia,* generic copies of the very same Sepracor "levalbuterol hydrochloride solutions" were "completely different" and thus Dey refused, yet again, Sepracor's efforts to permit consolidation. TRANSCRIPT OF TELEPHONE CONFERENCE ON JULY 19, 2006 (D.I. 27), at 6, lines 15-22.

Well after its initial ANDA filing, Dey filed its second ANDA, ANDA No. 78-309, with a paragraph IV certification seeking to copy another of Sepracor's drug products – this time Sepracor's "'levalbuterol solution concentrate.'" *See* DEY'S MEMORANDUM at 2, lines 16-17. Dey's notice letter concerning this further ANDA on one of Sepracor's other products was dated August 14, 2006 – over seven months after its first notice letter. Again, within the forty-five day period provided by the Hatch-Waxman Act, Sepracor filed suit on September 27, 2006. This second Dey case was assigned Civil Action No. 06-604-KAJ.

B. Dey's Assertion that the Dey I and II Actions Involve "Identical" Issues of Fact and Law Is Wrong

Sepracor does not dispute that the Dey I and II actions involve the same patents-in-suit. Since both actions involve the same patents-in-suit, it is no surprise that Dey's defenses and counterclaims regarding invalidity and unenforceability of such patents-in-suit are also the same in both the Dey I and II actions. Thus, for Dey, the issues on which it has the burden to prove are the same in the two actions. However, as to the issues on which Sepracor has the burden (*e g.*, infringement of the patents-in-suit), the Dey I and II actions involve different ANDAs and different products.[1] Thus, contrary to Dey's allegation, "[t]he questions of law and fact raised in the two actions brought by Sepracor against Dey" are not "identical." DEY'S MEMORANDUM at 3, lines 13-14.

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[1] Dey argues that, unlike the Complaint in the Dey I case, the Complaint in the Dey II case does not contain "an allegation of willfulness." DEY'S MEMORANDUM at 3 n.3. Dey is once again incorrect. In the Complaints for both the Dey I action and the Dey II action, Sepracor has alleged the cases to be exceptional under 35 U.S.C. § 285. *See, e.g.*, Dey I Complaint for Patent Infringement (D.I. 1), at ¶ 30 & Dey II Complaint for Patent Infringement (D I. 1), at ¶ 30. Dey's willfulness is a basis for exceptional case and Sepracor has put Dey on notice in this regard. *See, e.g*, Dey I Complaint for Patent Infringement (D.I. 1), at ¶¶ 24-25 & Dey II Complaint for Patent Infringement (D.I. 1), at ¶¶ 24-25.

Dey attempts to dismiss any argument that Sepracor would make regarding the different products at issue in the Dey I and II actions by stating that the accused products "differ only in the concentration of the active ingredient." DEY'S MEMORANDUM at 2, line 2 & 3, line 21. If such difference only relates to concentration, then one must ask why Dey went through the time and expense of filing separate ANDAs on the accused products and why this separate ANDA took over seven months longer for Dey to file and provide Sepracor with the requisite notice of such filing. *See* FDA GUIDANCE FOR INDUSTRY, VARIATIONS IN DRUG PRODUCTS THAT MAY BE INCLUDED IN A SINGLE ANDA at 3 (Dec. 1998) (stating that "[d]ifferent strengths or concentrations of a drug product . . . should be submitted in one original application . . . .") (attached hereto as Appendix B).

Moreover, if the questions of law and fact are identical and the difference in concentration is of no import, then Dey should be willing to admit on the record that the accused product in the Dey II action would necessarily infringe those claims of Sepracor's patents-in-suit that are found to be infringed by Dey's copies of Sepracor's "levalbuterol hydrochloride solutions" in the Dey I action. Not surprising, Dey has not done so.

C. Consolidation Without Modification of the Dey I Scheduling Order Would Prejudice Sepracor

When Sepracor sought consolidation in Massachusetts before any implications of an established scheduling order in the Breath case and on the very basis that Dey now claims – *i.e.*, "the interests of judicial economy, convenience, and expense," DEY'S MEMORANDUM at 4, lines 14-15 – Dey refused. Now, over eight months after the Dey I action was filed and some three months after discovery has been ongoing in the Dey I

action, Dey completely reverses its stance to the detriment of Sepracor's ability to prove its additional infringement case.

While Dey's proofs on issues of validity and unenforceability may be the same, consolidation of the Dey I and II actions would expand Sepracor's proofs on issues of infringement. The Dey II action involves a separate and later filed ANDA involving a different product. When Sepracor served discovery (both interrogatories and requests for documents) two and three months ago in the Dey I action, Sepracor was not focused on Dey's second ANDA with this different product. Moreover, Sepracor was not even aware of Dey's second ANDA when it negotiated the number of hours for deposition testimony and the number of interrogatories. All along, however, Dey could have informed Sepracor and this Court that a second notice letter based on a new ANDA and different product was forthcoming. Dey could have also produced this new ANDA, ANDA No. 78-309, in the Dey I action but has not.

While Dey needs no further modification of the discovery limits, Sepracor should not be prejudiced by Dey's delay in filing a second ANDA on a different product.

D. Consolidation With Modification of the Dey I Scheduling Order Would Not Prejudice Dey

Dey should not be heard to argue that it would be prejudiced by a modest increase in discovery limits (*e g.*, deposition hours and number of interrogatories) or by a reasonable enlargement of the existing calendar set forth in the Dey I Scheduling Order, as such increases and enlargements are necessitated due to Dey's own actions. It was Dey who refused to make possible consolidation with the Breath case in Massachusetts because the generic copies of Sepracor's "levalbuterol hydrochloride solutions," which are statutorily required to be bioequivalent, are "completely different." Further, Dey filed

a separate ANDA on a copy of Sepracor's "levalbuterol inhalation concentrate," a different product than the products already involved in the Dey I action, more than half a year after it filed its ANDA that is the subject of the Dey I Scheduling Order.

Moreover, Dey will not be prejudiced by an enlargement of the calendar in the Dey I matter since, in any event, Dey can not obtain FDA approval or engage in commercial marketing of a copy of Sepracor's "levalbuterol hydrochloride solutions" until after resolution of the Breath action in Massachusetts. *See* SEPRACOR'S LETTER TO JUDGE DATED JULY 17, 2006 (D.I. 24), at 2, lines 22-32. Dey would also not be prejudiced by applying the calendar of the enlarged Dey I Scheduling Order to the Dey II action because Dey will obtain the alleged efficiencies and conveniences of the consolidated actions. Moreover, Dey has no one but itself to blame for its delay in filing this new ANDA and thereby providing notice to Sepracor more than half a year after the Dey I action was filed.

Accordingly, Dey will not be prejudiced by consolidating the Dey I and II actions with an increase in both the discovery limits and calendar of the Dey I Scheduling Order.

III. CONCLUSION

For the foregoing reasons, the Court should deny Dey's motion to consolidate the Dey I and Dey II action unless it modifies the Dey I Scheduling Order to modestly increase the discovery limits and reasonably enlarge the calendar.

November 7, 2006

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CERTIFICATE OF SERVICE

The undersigned counsel certifies that, on November 7, 2006, he electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

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The undersigned counsel further certifies that, on November 7, 2006, copies of the foregoing document were sent by email and hand to the above local counsel and by email and first class mail to the following non-registered participant:

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APPENDIX A

Dadio, Susan

From: John.Kling@dey.com
Sent: Tuesday, February 07, 2006 9:44 PM
To: Susan Dadio
Cc: DormanR@hbdlawyers.com
Subject: RE: Dey ANDA No. 77-800

Thanks, Susan. Rod will be in touch

John

"Susan Dadio" <Susand@burnsdoane.com>
02/07/2006 06:10 PM

To: <John.Kling@dey.com>
cc: <DormanR@hbdlawyers.com>
Subject: RE: Dey ANDA No. 77-800

John:

Thank you for your message. Pursuant to your request, please find attached a copy of the Amended Complaint filed in the District Court of Massachusetts with regard to the action brought against Breath Limited related to its AND Notification for levalbuterol hydrochloride inhalation solutions. Given the time constraints for such matters, we look forward to hearing from you or Mr. Dorman as soon as possible.

Sincerely,
Susan

-----Original Message-----
From: John.Kling@dey.com [mailto:John.Kling@dey.com]
Sent: Tuesday, February 07, 2006 8:34 PM
To: Susan Dadio
Cc: DormanR@hbdlawyers.com
Subject: RE: Dey ANDA No. 77-800

Susan:

Yesterday, you asked if we would consent to a consolidation of Sepracor's potential suit with Breathe's in Massachusetts' Federal District Court. In order to help us in our decision, would you kindly send us a copy of your Complaint against Breathe? I will be leaving on vacation tomorrow, so please copy our Lead Litigation Counsel, Rod Dorman on

your reply. You may also call Rod directly to discuss this or any other aspect of this matter
at: (213) 694-1006. Rod is senior partner at Hennigan Bennett & Dorman in LA. His email address should be shown above.

Thanks,

John

John Kling
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REDACTED

APPENDIX B

Guidance for Industry

Variations in Drug Products that May Be Included in a Single ANDA

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
December 1998

OGD 2

98D-1268

GDL 1

Guidance for Industry

Variations in Drug Products that May Be Included in a Single ANDA

Comments and suggestions regarding this document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the guidance. All comments should be identified with the docket number provided at the beginning of the notice. Submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Parklawn Dr., rm. 1061, Rockville, MD 20852.

After the comment period closes, comments should be provided in writing to the Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

Additional copies are available from:

Office of Training and Communications
Division of Communications Management
The Drug Information Branch, HFD-210
5600 Fishers Lane, Rockville, MD 20857
(Tel) 301-827-4573
(Internet) http://www.fda.gov/cder/guidance.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
December 1998
OGD 2

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GUIDANCE FOR INDUSTRY[1]

Variations in Drug Products that May Be Included in a Single Abbreviated New Drug Application

I. INTRODUCTION

This guidance is intended to provide information to applicants on certain specific variations of a drug product that should be included in a single abbreviated new drug application (ANDA) and describe the general factors to be considered when determining whether single or multiple ANDAs should be submitted.

Prior to October 1, 1990, applicants were to submit separate ANDAs for each drug dosage form and for each variation (e.g., strength or color) within a dosage form. Historically, applications were separated for ease of review and postapproval tracking. On October 1, 1990, the Office of Generic Drugs (OGD) issued the Interim Policy and Procedure Guide (PPG) 20-90. This guide permitted certain variations of solid oral dosage forms and injectable to be submitted within a single abbreviated application. On June 7, 1995, PPG 20-90 was amended to allow certain variations to be submitted as supplements.

This guidance incorporates the policies and procedures in PPG 20-90, clarifies the practice of including variations of products in a single application, and reduces the burden on industry for submitting and maintaining separate applications for certain variations of the same drug product.

II. GENERAL CONSIDERATIONS

To minimize disruption of the review of pending applications, OGD recommends that applications that have already been submitted but not approved be maintained as submitted. To aid in administrative tracking, OGD also suggests that applications submitted before December 31, 1998, continue to follow the policies described in OGD PPG 20-90. For applications submitted after December 31, 1998, OGD recommends that applicants refer to this guidance to determine whether one or more ANDAs should be submitted for variations of a specific drug product dosage form.

A. Reference Listed Drugs (RLDs)

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[1] This guidance has been prepared by the Office of Generic Drugs in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. This guidance represents the Agency's current thinking on variations in drug products that may be included in a single abbreviated application. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statue, regulations, or both

To determine which variations of a product should be included in a single abbreviated application, the initial consideration is whether there are separate NDAs as reference listed drugs (RLDs) or whether there is a single NDA as a RLD. (For example, when the same drug product is used for two separate indications, that product might have two separate NDAs as RLDs.) Generally, when there is a separate NDA as a reference listed drug for a specific drug product there should be a separate abbreviated application for that NDA. However, as described in sections B through G of this guidance, this will not always be the case.

B. Multiple Bioequivalence Studies

Separate ANDAs should be submitted when, because of certain variations in the drug product (e.g., formulations, shapes), an in vivo bioequivalence study cannot be waived (21 CFR 320). Examples of this situation include:

- Formulation Differences. Two products should not be included in the same application if two strengths of a capsule have differences in formulation or if there are questions about absorption of the products so that an in vivo bioequivalence waiver would not be granted for the lower strength, even if a bioequivalence study was performed on the higher strength (21 CFR 320.22(d)(2)).

- Multiple combinations of strengths, shapes, and colors for oral solids. Where there are such multiple combinations, separate in vivo bioequivalence studies should be performed and separate applications should be submitted (21 CFR 320.22(d)(4)).

More specific guidance on this can be found in Section III, Specific Dosage Forms.

There are instances when a single ANDA can be submitted even if the application includes more than one bioequivalence study. For example, if there are five strengths of a product and there is acceptable proportionality of inactive ingredients, but the Division of Bioequivalence (DBE) has suggested separate bioequivalence studies on the lowest and highest strengths, all five strengths may be included in the same application. In this case, the studies are not related to a difference in formulation but have been recommended to ensure the equivalence of a product across a wide range of strengths.

C. Different Excipients

Any product variations because of differences in excipients (e.g., absorption enhancers or hydrophobic agents) or other changes in formulation that may significantly affect absorption of the active drug ingredient or active moiety should be submitted in separate applications. This would include products with differences in excipients where separate

bioequivalence studies are recommended.

Topical products with differences in excipients where separate in vivo demonstration of bioequivalence is recommended should be submitted in separate applications.

D. Different Dosage Forms

Different dosage forms should be submitted in separate applications. (See the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations.)*

E. Pharmacy Bulk Packages

Pharmacy bulk packages should always be submitted as separate applications. Strengths or fill volumes for pharmacy bulk packages that can share a single application should be determined based on the RLD.

F. Different Strengths or Concentrations

Different strengths or concentrations of a drug product or combination product, if they are the same dosage form, intended for the same route of administration, and have the same indications, should be submitted in one original application when their qualitative composition is the same. (See Section IV for additional guidance.)

***G.* Different Container Sizes and Configurations**

Except for pharmacy bulk packages, products utilizing different container sizes, configurations, and materials (e.g., glass or plastic) of one finished pharmaceutical product intended to be used for the same route of administration and for the same indications (consistent with the RLD) may usually be included in a single application, within certain limitations.

In general, separate applications should be submitted for special packaging systems. In this context, ***special packaging*** may describe novel or technologically new container closure systems or packaging to serve the special needs of the intended population. A major consideration in deciding if single or multiple ANDAs would be recommended is whether significantly different manufacturing processes for which there is **little** experience would be used in the special packaging. Because of the range of possibilities that special packaging provides, such applications will generally be treated on a case-by-case basis. If applicants are considering novel or nontraditional processes for packaging, it is suggested that the specific situations should be discussed with OGD prior to submitting applications.

Different packaging formats in which the drug delivery device is integral to the use of the product usually should be submitted as separate applications. In this case the

manufacturing process for the packaging format may be a consideration. Examples include syringes, aerosol or pressurized (powered) dispensers versus manually operated pump dispensers, and product-loaded swabs versus applicator bottles or separate solutions and applicators. Unit and bulk packed product-loaded swabs, however, could be included in a single application.

III. SPECIFIC DOSAGE FORMS

The considerations for more prevalent specific dosage forms are detailed below. For dosage forms not specifically covered, please refer to Section II - General Considerations. The recommendations in Section III are intended to provide the applicant with sufficient information to determine whether separate applications should be submitted for other dosage forms. If there are still questions, the OGD should be contacted for assistance.

A. Solid Oral Dosage Forms

The chart below is a restatement of the information set forth in PPG 20-90. Applicants should limit the number of variations in a single application. Limiting the variations makes the review process simpler and allows more accurate tracking of postapproval changes. Only the following combinations of strengths, color, and shapes should be included in a single application.

SOLID ORAL DOSAGE FORMS

One strength One color One shape	–	Single application
One strength One color Multiple shapes	–	Single application
One strength Multiple colors One shape		Single application
Multiple strengths One color One shape		Single application
Multiple shapes	–	Only one color per shape per strength should be submitted in a single application. Different combinations should be submitted in separate

applications.

B. Parenteral Products

Each application for a parenteral product should be limited to a common formulation. When more than one strength of a product exists, some small formulation differences may be included in a single application. A common example of such a difference is the amount of inactive ingredient needed to produce tonicity. Preserved and nonpreserved formulations, however, are considered to be different formulations, and separate applications would be recommended.

Varying fill volumes (e.g., 2, 5, and 20 mL vial sizes) may be included in the same application, but drug products with different container materials or packaging systems should be submitted as separate applications.

PARENTERAL SOLUTIONS AND SUSPENSIONS

One formulation One strength	–	Single application
One formulation Multiple strengths	–	Single application
Multiple formulations (e.g., preserved or unpreserved) One strength	–	Multiple applications*
One formulation One strength Multiple fill sizes		Single application**

One formulation One strength One or multiple fill sizes, Multiple packaging types, or container materials	–	Multiple applications, depending on the number of package types and/or container materials used

*Some small formulation differences, such as the amount of an inactive ingredient needed to maintain tonicity, may be included in a single application with different strengths. Additionally, each application should be limited to a single dosage form.

** Except Pharmacy bulk packages. Pharmacy bulk packages should always be submitted as separate applications.

PARENTERAL STERILE SOLIDS

One formulation One or multiple fill quantities Single container/closure system	=	Single application
One formulation One or multiple fill quantities Multiple container/closure systems	–	Multiple applications
Multiple formulations		Multiple applications

C. **Transdermal Products**

The method of manufacture of a transdermal product usually determines whether one or more applications would be recommended. For example, if the active ingredient is contained in the patch adhesive, the same application should not contain submission data for a product where the active ingredient is contained in a reservoir. Transdermal systems of the same size which release different amounts of the active ingredient through a membrane should be submitted in separate ANDAs, because each strength uses different manufacturing procedures and controls. However, transdermal products in which the active ingredient is in the same component of the patch, but product strength depends upon the patch size, should be in a single application.